without prejudice to filing a divisional application. It is also noted that the omitted subunit *E. coli* O157:H7 antigens prepared from the O-specific polysaccharide of *E. coli* O157:H7 will be the subject of a continuing application, if desired in due course.

It is respectfully asked that the Examiner kindly enter the current amendment in the record, albeit after a final rejection. The Examiner fully searched the art and found no teaching or inference of a vaccine containing inactivated or killed whole *E. coli* O157:H7 in admixture with the metabolizable oil adjuvant as taught in the application. The claims, if amended as proposed, do not present any new issues requiring further search. Since the amendment relevant to the whole cell of the invention requires only a cursory review by the Examiner, Applicants hope that the proposed amendment will be entered and considered in a favorable light.

In accord with 37 C.F.R. § 1.121, the amendment to the claims and a complete listing of all claims begin on a separate sheet. Only the claim number and status indicate the canceled claims. For the convenience of the Office staff, the amendment is placed in the below Appendix and incorporated herein by reference thereto. The amendment adds no new matter. Claims 22 and 23 provide the subject matter of Claims 20 and 21 that is believed to be allowable, but rewritten for the better readability thereof. Support for indicating that the vaccine is administered in an effective amount to animals is found from page 7, line 14 to page 8, line 3 of the specification, and elsewhere.

The present amendment overcomes the rejection of Claim 20 (now Claim 22) under 35 U.S.C. § 102(b) as being anticipated by Finlay *et al.* and the rejection of Claim 21 (now Claim 23) under 35 U.S.C. § 103(a) as being unpatentable over Finlay *et al.* in view of Brashears *et al.* Specifically, Applicants' claimed invention, as amended, is neither anticipated nor rendered obvious by the art.

Finlay *et al.* only describe compositions that employ the EHEC cell culture supernatant ("CCS") derived from an *E. coli* culture with or without supplementation of EHEC secreted proteins. Finlay *et al.* define the EHEC CCS explicitly as a supernatant that is substantially free of EHEC bacterial cells or lysate of such cells [0055]. When making the concentrated CCS, the whole cells are removed by centrifugation [0107]. Finlay *et al.* do not describe the use of any bacterial vaccine, let alone Applicants' novel inactivated or killed whole *E. coli* bacterin as a vaccine for reducing the shedding of *E. coli* O157:H7. There is no anticipation.

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Since Finlay *et al.* advocate the use of the EHEC CCS that is substantially devoid of EHEC bacterial cells, the disclosure, in effect, teaches away from the use of whole *E. coli* O157:H7 to elicit an immune reaction. Finlay *et al.* discard the whole cells as worthless because they see no benefit to the whole bacterial cell. It is plain to see that the negative teachings of Finlay *et al.* would not motivate the practitioner to use the whole bacterial cells, let alone combine *E. coli* O157:H7 with the lactic acid bacteria of Brashears *et al.*

Moreover, there is no teaching or suggestion that the vaccine of Finlay *et al.* should be supplemented with lactic acid bacteria, *i.e.*, the competitive exclusion product of Brashears *et al.* The immune activity of a systemic bacterial vaccine has a very different mechanism of action than the exclusionary activity of the probiotics in the intestinal tract. Predictability of whether the combination would enhance or interfere with each other's diverse properties and modes of action is totally lacking without substantial experimentation. Consequently, the combined art does not render the claimed invention obvious.

In view of the proffered amendment and the foregoing remarks, it is respectfully asked that the rejections of the pending claims be withdrawn and the application be allowed.

Favorable treatment is respectfully urged.

Respectfully submitted,

WYETH

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